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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/845,741	05/01/2001	Samuel T. Henderson	ACC.01	3451

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EXAMINER

BAHAR, MOJDEH

ART UNIT	PAPER NUMBER
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1617

DATE MAILED: 07/15/2003

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Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/845,741

Applicant(s)

HENDERSON, SAMUEL T.

Examiner

Mojdeh Bahar

Art Unit

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 28 April 2003.
- 2a) ☐ This action is FINAL. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-4,7 and 11 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration:
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-4,7 and 11 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____.
- 4) ☐ Interview Summary (PTO-413) Paper No(s). _____.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other:

DETAILED ACTION

Continued Examination Under 37 CFR 1.114

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on April 28, 2003 has been entered.

Claims 1-4, 7 and 11 are herein examined on the merits.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1-4, 7 and 11 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. Note that the specification does not support the **negative proviso** added to the claims that **"a patient have a diet wherein carbohydrate intake is not restricted"**. In fact, pages 8-10 to which the applicant refers to low carbohydrate intake and its physiological effects in general, and ketone body production specifically.

Claims 1-4, 7 and 11 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for treatment of Alzheimer's, does not reasonably provide

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enablement for **prevention** therefor. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to use the invention commensurate in scope with these claims. It is not clear how one could prevent alzheimer's disease. As stated by the applicant on page 1 of the specification no effective prevention of alzheimer's is known in the art. Moreover, the Skilled Artisan would not know how to select the patient in which this preventive therapy would work. The instant specification fails to provide information that would allow the skilled artisan to practice the instant invention without undue experimentation. Attention is directed to *In re Wands*, 8 USPQ2d 1400 (CAFC 1988) at 1404 where the court set forth the eight factors to consider when assessing if a disclosure would have required undue experimentation. Citing *Ex parte Forman*, 230 USPQ 546 (BdApls 1986) at 547 the court recited eight factors:

- 1) the quantity of experimentation necessary,
- 2) the amount of direction or guidance provided,
- 3) the presence of absence of working examples,
- 4) the nature of the invention,
- 5) the state of the prior art,
- 6) the relative skill of those in the art
- 7) the predictability of the art, and
- 8) the breadth of the claims.

Applicant fails to set forth the criteria that defines the patient of this preventive therapy, i.e., how would the Skilled Artisan know who needs preventive therapy? Additionally, Applicant fails to provide information allowing the skilled artisan to ascertain how Alzheimer

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related dementia can be prevented. In the instant case, the specification contains no showing of prevention in any population, thereby failing to provide sufficient working examples. Applicants fail to provide information sufficient to practice the claimed invention, absent undue experimentation.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1,7 and 11 rejected under 35 U.S.C. 102(b) as being anticipated by Blackburn (USPN 4,528,197).

Blackburn teaches a method comprising administering an emulsion of MCT to a patient. Given that a compound/composition and its properties are inseparable, the dementia preventing qualities of the composition is inherent in the method of Blackburn.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 1-4, 7 and 11 are rejected under 35 U.S.C. 103(a) as being unpatentable over Veech (USPN 6,316,038).

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Veech (USPN 6,316,038) teaches a method for treating Alzheimer's disease and its symptoms and manifestations, including dementia, employing a ketogenic (medium chain triglycerides) diet, see col. 3, lines 21-59 in particular. Veech (USPN 6,316,038) teaches an example of a ketogenic diet wherein at each of the three meals the patient consumes 48-50 g of fat, see particularly col. 10, lines 56-67. Veech (USPN 6,316,038) further teaches that increase of ketone bodies is effective in the treatment of Alzheimer's disease, see particularly col.5, lines 11-29. Veech also teaches that both oral and parenteral administration of triglycerides can increase blood ketones, see col. 9 lines 62-65, see also col. 20, lines 16-23.

It would have been obvious to one of ordinary skill in the art at the time the invention was made to employ medium chain triglycerides in a method of treating Alzheimer's disease and dementia associated therewith.

One of ordinary skill in the art would have been motivated to employ medium chain triglycerides in a method of treating Alzheimer's disease and dementia associated therewith because medium chain triglycerides are known to increase the level of ketone bodies in the blood and the increase of ketone bodies in the blood is known to be useful in treating Alzheimer's disease. Therefore one of ordinary skill in the art would be motivated to increase ketone bodies in order to treat Alzheimer's.

Response to Arguments

Applicant's arguments filed April 28, 2003 have been fully considered but they are not persuasive. Applicant argues that the prior art references teach ketogenic diets whereas the claims herein teach the administration of MCT outside of the context of a ketogenic diet. Applicant also argues that in providing that triglycerides can only be administered in a diet of

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low protein and carbohydrate, the prior art references teach away from the instant invention, Note that the portions of Veech quoted by the applicant, e.g., col. 9, are portions in which Veech describes the prior art and the shortcomings thereof. The method of treating alzheimer's disease taught by Veech does not require adherence to a ketogenic diet. In fact, the advantage of Veech over the prior art is the absence of the ketogenic diet. In column 17 Veech states:

"The advantage of using ketone bodies themselves are several. Firstly, provision of ketone bodies themselves do not require the limitation of carbohydrates, thus increasing the palatability of the dietary formulations." See col. 17, lines 16-27.

As can be seen by the above quotation the instant claims are indeed rendered obvious by the prior art reference herein.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Mojdeh Bahar whose telephone number is (703) 305-1007. The examiner can normally be reached on (703) 305-1007 from Monday to Friday from 9:00 a.m. to 5:00 p.m.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Sreeni Padmanabhan, can be reached on (703) 305-1877. The fax phone number for the organization where this application or proceeding is assigned is (703) 308-4556.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-1235.

Mojdeh Bahar
Patent Examiner
July 12, 2003


RUSSELL TRAVERS
PRIMARY EXAMINER